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A SINGLE CENTER EXPERIENCE OF ATRIAL FIBRILLATION ABLATION WITH CRYOBALLOON

KRİYOBALON İLE TEK MERKEZDE ATRİYAL FİBRİLASYON ABLASYONU DENEYİMİ

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Abstract

Aim: Electrical isolation of the pulmonary veins is known as the fundamental of for atrial fibrillation (AF) treatment invasively, and thus, has been suggested as the first-line therapy in AF curation. In this study, we presented our single center pulmonary vein isolation (PVI) experience and long-term clinical outcome.

Methods: One hundred and six symptomatic AF patients resistant to medical therapy underwent cryoablation of the pulmonary veins. Participants were divided into two groups regarding AF categorization as persistent or paroxysmal. Recurrence and peri-procedural complications were evaluated after the treatment.

Results: A 106 patients, 67 males (63.2%), with mean age of 51.8 ±13.1 years, underwent cryoablation. While the paroxysmal AF group was composed of 90 patients (84.9%); the persistent AF group consisted of 16 patients (15.1%). The procedure mean time was 115,9±9,1 minute while the fluoroscopy mean time was 29,2±5,6 minutes. A total of 8 (7.5%) non-fatal complications were experienced. A total of 18 recurrences (17%) were observed during mean duration of 25.2 months follow-up period. The survival rates without AF were 85.6% and 61.8 % in in the paroxysmal and persistent groups, respectively.

Conclusions: The cryoballoon PVI seems to be a successful and reliable method of treating AF and may be preferred as a primary procedure even in patients with persistent AF.

Keywords: Atrial fibrillation, cryoballoon, phrenic nerve palsy

Öz

Amaç: Pulmoner venlerin elektriksel izolasyonu, atriyal fibrilasyonun (AF) invaziv tedavisinin temel taşı olarak bilinir ve bu nedenle, AF ablasyonunda ilk adım olarak önerilmiştir. Bu çalışmada, persistant ve paroksismal AF tanısı koyulan hastalarda pulmoner ven izolasyonu (PVI) deneyimimizi ve klinik sonuçlarımızı analiz ettik.

Yöntemler: Antiaritmik tedaviye dirençli semptomatik AF'si olan ardışık yüz altı hastaya pulmoner venlerin izolasyonu için kriyoablasyon uygulandı. Hastalar AF sınıflamasına göre persistant veya paroksismal olmak üzere iki gruba ayrıldı. Rekürrens ve peri-prosedürel komplikasyonlar sırasıyla birincil ve ikincil sonuçlar olarak analiz edildi.

Bulgular: Yaş ortalaması 51,8 ±13,1 yıl, 67'si erkek (%63,2) olan 106 hastaya kriyoablasyon tedavisi uygulandı. 90 hastada paroksismal AF (%84,9) ve 16 hastada persistant AF (%15,1) vardı. Ortalama işlem süresi 115,9±9,1 dakika ve ortalama floroskopi süresi 29,2±5,6 dakikaydı. Ölümcül olmayan 8 (%7,5) komplikasyon gözlendi. İşlem sonrası 3 aylık dönem çıkarıldığında ortalama 25,2 aylık takip süresinde 18 nüks (%17) gözlendi. Paroksismal ve persistan gruplarda AF'nin nükssüz oranları sırasıyla %85,6 ve %61,8'idi.

Sonuç: Kriyobalon ile pulmoner ven izolasyonu AF tedavisinde başarılı ve güvenilir bir yöntem olarak görünmektedir. Sonuçlarımız, kriyoablasyonun persistant AF'si olan hastalarda bile başlangıç tekniği olarak kullanılabileceğini gösteren önceki çalışmalarla uyumludur.

Anahtar Kelimeler: Atriyal fibrilasyon, kriyobalon, frenik sinir paralizisi

Introduction

Clinical atrial fibrillation (AF) is described as the detection of an AF episode by 12-lead electrocardiography (ECG) or any documentation of an AF episode longer than 30 seconds in 24 hours ECG Holter. AF is an important disease that is of great interest for clinicians both clinically, economically and in terms of mortality and morbidity, and which can be avoided by different management modalities. The incidence of AF in the adult population is 2-4%[1].

In recent guidelines, in addition to medical treatment in AF, AF ablation seems to be one step ahead of medical treatment that the increased data on the provision of cure with ablation. After the detection and classification of clinical AF, evaluation of the patient for complications of AF and ensuring sinus rhythm as soon as possible is the primary goal in accordance with the new modalities[1]. The main target aimed at AF ablation is the electrical inaccessibility of pulmonary veins. In the current studies, a success rate of over 80% was reported in long-term follow-up after successful AF ablation procedure[2]. In the recent guidelines, pulmonary vein isolation (PVI) is the primary suggested non-drug cure option for both persistent and paroxysmal symptomatic AF patients who are resistant to medication[3-5].

In this study, we aimed to show our clinic's (a referral arrhythmia center) experience of electrical isolation through cryoballoon of pulmonary veins in AF patients.

Materials and Methods

- *Study population*

The individuals treated by cryoablation because of AF between May 2016-December 2018 were retrospectively examined in this study. In all procedures, the second-generation cryo energy balloons were used (Arctic Front Advance Cardiac Cryoablation Catheter System, Medtronic, Inc Minneapolis, MN). AF episodes shorter than 7 days (conversion to sinus rhythm with spontaneous or medical treatment) were defined as paroxysmal and AF episodes longer than seven days were described as persistent AF[3]. The patient's anamnesis and examinations' notes (ECG, echocardiography, 24 hours ECG Holter and blood parameters) were obtained from the visit notes and the hospital records.

Exclusion criteria were intermediate-advanced valve pathologies (stenosis and insufficiency), congenital heart diseases, bleeding diathesis, contraindications for any anticoagulants, detection of thrombus in transesophageal echocardiography, advanced-stage heart failure, and left atrial diameter bigger than 5.5 centimeters. All patients were given detailed information about the procedure, success rate, and risks, and the consent forms were signed. Kosuyolu Research and Education Hospital of Medicine Clinical Research Ethics Committee approved this study with number and date of 06.10.2020/9/356. The study was conducted in keeping with all ethical procedures/standards and the Declaration of Helsinki.

- *Preprocedural management*

Hemogram, kidney and thyroid functions, liver enzymes, and prothrombin time parameters were examined in all patients before the procedure. Before ablation, patients were evaluated for ejection fraction (EF), valve pathologies, and left atrium diameter by transthoracic and transesophageal echocardiography[6]. It was shown that there were no intracardiac thrombi for all patients. Anticoagulation therapy was started at least 3 weeks prior to the procedure and anticoagulation was continued without interruption during ablation. The International Normalized Ratio (INR) value was ensured the level of between 2 and 3 before the procedure in warfarin user patients. The patients taking a new generation of oral anticoagulants

(NOACS), took their last doses 12-24 hours prior to the ablation depending on NOAC type.

- *Ablation procedure*

Ablation was performed with local anesthesia (lidocaine) and sedation (midazolam, fentanyl) for all patients. 2 pieces of 6 French vascular sheaths were positioned in the left femoral vein and another 8 French vascular sheath was positioned in the right femoral vein access. Coronary sinus and quadripolar diagnostic catheters were engaged into the coronary sinus and his area from the left femoral vein access. The septostomy procedure was performed using fluoroscopic anatomy. The vascular sheath in the right femoral vein was replaced with a SL-1 septostomy sheath (Abbott, Chicago, IL, USA) with the help of a 0.32 wire and SL-1 was positioned into the superior vena cava. After insertion of the Brockenbrough needle (BRK-1, Abbott) into the SL-1 catheter, the catheter was withdrawn and when it reached the patent foramen ovale (PFO) region, the needle was removed from the catheter tip and the septostomy procedure was performed. After confirming with a contrast agent and 0.014 floppy wire that the needle tip was in the left atrium, the SL1 catheter was advanced into the left atrium (Figure 1). A 0.35 guidewire was sent into the SL1 catheter, and the catheter was replaced with a (FlexCath Advance) steerable sheath (Medtronic). A 20- or 25-mm circular (Achieve™) mapping catheter (Medtronic) and a 28mm cryoballoon catheter were advanced from the steerable sheath.

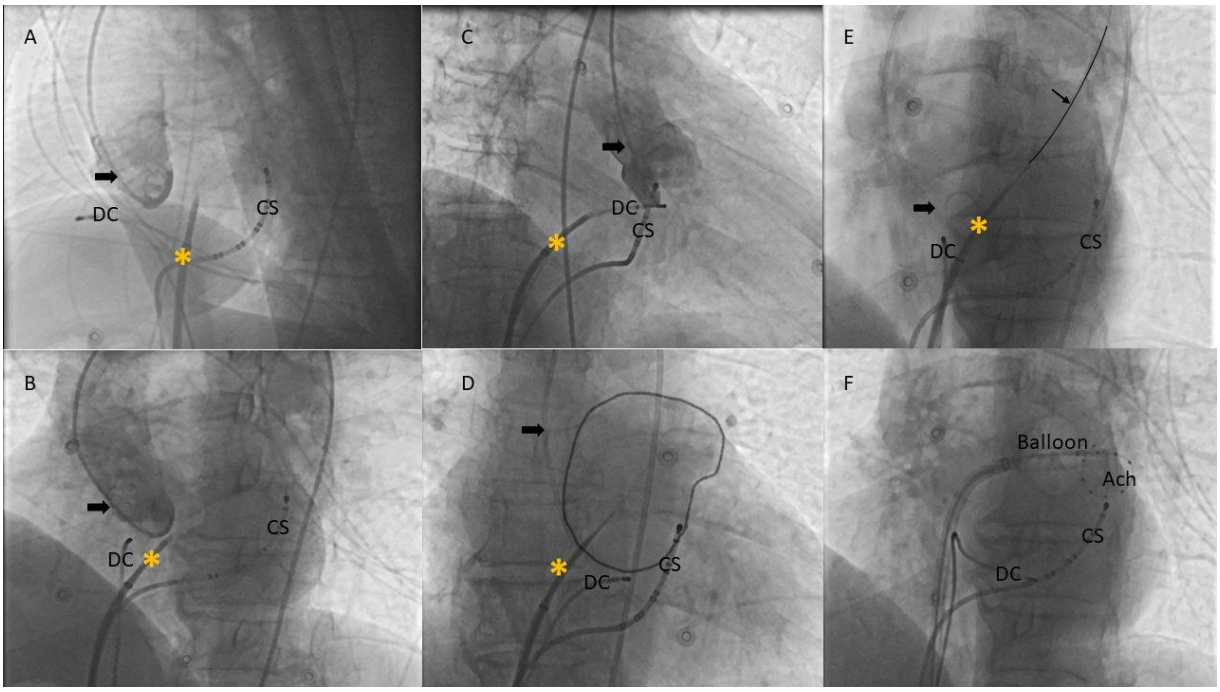

Figure 1: Transseptal puncture guided by fluoroscopic anatomy.
Figure 1 shows transseptal puntruce of a patient by fluoroscopy guidance.
A: Left lateral (90^0) fluoroscopic view shows the position of the septostomy sheath posterior to the aorta.
B: Left anterior oblique (30^0) fluoroscopic view shows the position of the septostomy sheath.
C: Right anterior oblique (30^0) fluoroscopic view shows the position of the septostomy sheath.
D: Contrast enhancement of the left atrium with opaque administation after septostomy.
E: Wiring of left upper pulmonary vein with floppy after septostomy to prevent injury of the left atrium.
F: Achieve and cryo-ballon catheter positioned towards to the left inferior pulmonary vein.
*: septostomy sheath, DC: diagnostic catheter, CS: coranary sinus, Ach: achieve circular mapping catheter, Thick arrow: pigtail positioned in non-coranary cuspis, Thin arrow: 0.014 wire positioned in the left upper pulmonary vein, Straight line: Left atrium border

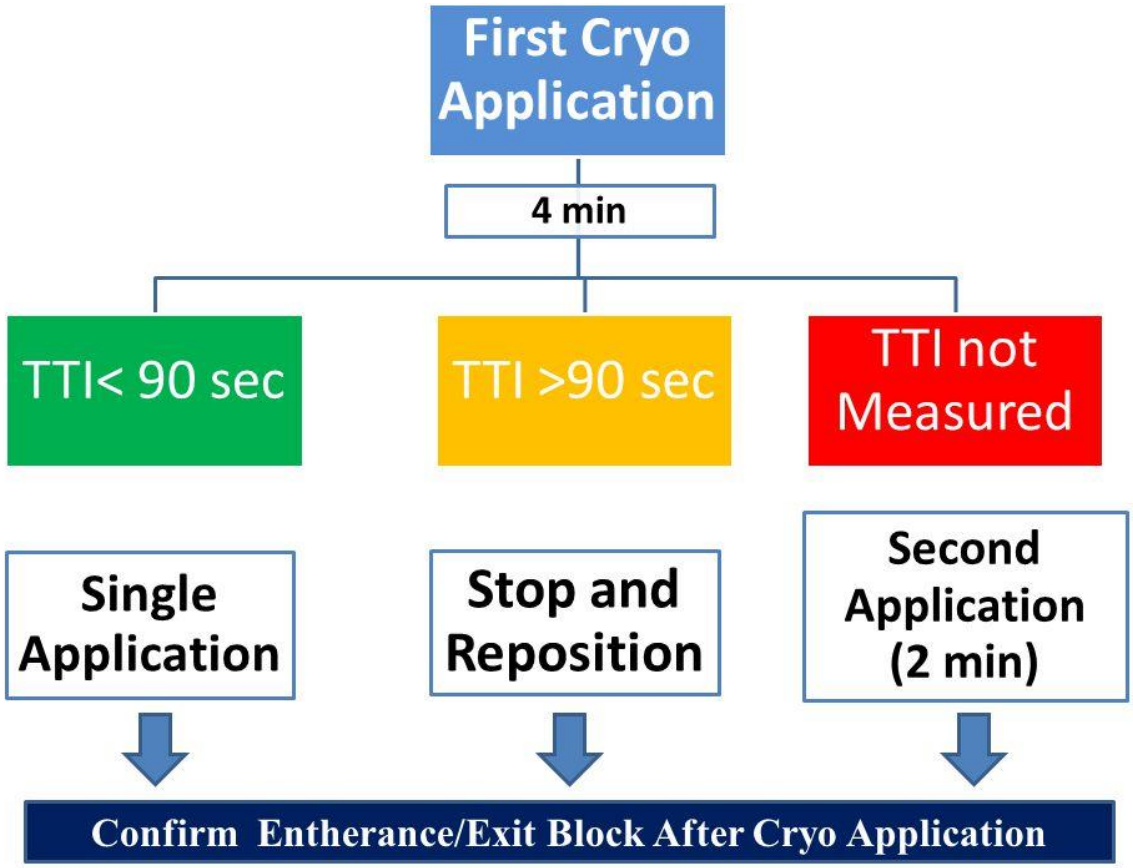

Figure 2. Freezing Protocol (Figure 2 shows the number and time of cryoenergy applications in each pulmonary vein varied as a function of the time necessary to achieve electrical isolation of the vein.)
TTI: time to isolation.

After taking the electrical potentials of the pulmonary vein with a circular catheter from the pulmonary vein ostium, the cryoballoon catheter was inflated and advanced to the pulmonary vein ostium (Figure 1). Cryoablation was started after the selective stop-flow or slow-flow pulmonary contrast imaging. The dissociation or disappearance of pulmonary vein potentials (time-to-isolation) was followed up with the circular mapping catheter. If the pulmonary vein isolation was achieved within 90 seconds, only a single ablation of 240 seconds was performed. If it was not isolated for over 90 seconds, the balloon was deflated, repositioned and the ablation was performed again. If the insulation phase could not be quantified upon the need to advance the balloon to a better position with the aim of PV occlusion, distinct two application as 240 and 120 seconds was used (Figure 2). In order to prevent phrenic nerve paralysis while cryoenergy was applied to the right pulmonary veins, the decapolar catheter was placed in the superior vena cava (SVC) region and stimulation of phrenic nerve was performed with electrical stimulus (2500 msec cycle). Tactile feedback of diaphragmatic contraction method was used to assess the phrenic nerve function loss.

After ablation, if the rhythm was AF, electrical cardioversion was executed for achieving sinus rhythm, then pulmonary veins were shown, via exit and entrance blocks, to be electrically isolated.

Transthoracic echocardiography was executed immediately after ablation to evaluate possible pericardial effusion.

- *Postprocedural management*

Patients were followed up in the in-patient department with an ECG and non-invasive blood pressure monitoring if no complications were observed after the procedure. After the bleeding control was achieved, the patient was given anticoagulation therapy (if NOACs were used, the NOACs dose was given to the patients, and if warfarin was used, the warfarin dose determined for that day was given to the patients). The morning after the ablation, the patients were examined, and their treatment was reconsidered and discharged.

- *Follow-up period*

Ablation success was described by way of the nonappearance of atrial arrhythmia (atrial tachycardia, fibrillation or flutter) over 30 seconds after a blanking period of 3 months from the ablation procedure[5]. The follow-up was performed with 1st and 12th-month echocardiography; 1st, 3rd, 6th, and 12th month ECG; 12th-month 24-hours ECG Holter. Long-term follow-up (>1-year post-intervention) was completed once a year. Patients were also followed up by phone calls. It was suggested to the patients that if they felt any palpitations within any period of time, they should take ECG.

- *Statistical analysis*

While categorical variables were stated by ratios scheme and compared with chi-square test, continuous data were expressed with mean±SD scheme and assessed with student-T and paired T-tests. The Kolmogorov-Smirnov test was applied to check the normally distribution. In the following process AF recurrence was assessed with the Kaplan–Meier method. Event-free time was considered from the procedure day to the recurrence day or the last day of the patient's hospital visit.

Patients who had no recurrence of AF by the last follow-up were assumed as the event-free patient. The Kaplan–Meier curve for event-free analysis was drawn to assess the recurrence between groups, divided recurrence, and non-recurrence group. Univariate regression analysis was executed to define the crucial parameter on AF recurrence. In addition, parameters that showed the recurrence well were evaluated by the multivariate COX regression analyses. Statistical analyses were executed through the SPSS Statistics software (Windows v. 20, IBM) and statistically significance was defined as the p values of under the 0.05.

Results

106 patients were included in this study. While 90 patients had paroxysmal AF, 16 patients diagnosed with persistent AF. There was a male predominance (63.2%) with mean age of 51±13 years. The mean time of procedure and fluoroscopy were 115.9±9.1 and 29.2±5.6 minutes, respectively. The patients were followed averagely 25.2±15.5 months. The baseline characteristics and procedural characteristics are summarized in Table 1.

During the follow-up (25.2 months) AF recurrence was observed in 18 patients (17%). A statistically significant lower recurrence rate was observed in the paroxysmal AF group than in the persistent AF group (p=0.05). Recurrence was observed for 13 patients (14.4%) in the paroxysmal AF group and 5 patients (31.2%) in the persistent AF group (p=0.0032) (Figure 3).

The AF recurrence predictors were ejection fraction (p=0.004), left ventricular end-diastolic diameter (p=0.005), left atrium (LA) diameter(p<0.001), and persistent AF (p=0.05). LA diameter was determined as an independent predictor in multivariate regression analysis (p=0.05).(Table 2)

Table 1. Demographic and clinical variables

	AF Recurrence (-) 88 (83%)	AF Recurrence (+) 18 (17%)	Total 106	P
Gender Female n %	34 (38.6 %)	5 (27.8 %)	39 (36.8%)	0.547
Male n %	54 (61.4%)	13 (72.2 %)	67 (63.2%)	
Age (years) ±SD	52.1 ±12.5	50.1 ±15.8	51.8 ±13.1	0.554
BMI (kg/m^2) ±SD	26.9 ±2.8	27.2 ±2.7	26.9 ±2.8	0.685
CAD n %	7 (8%)	1 (5.6%)	8 (7.5%)	1.000
Hypertension n %	36 (40.9%)	6 (33.3%)	42 (39.6%)	0.738
Diabetes Mellitus n %	14 (19.3%)	4 (22.2%)	21 (19.8%)	1.000
Hyperlipidemia n %	15 (17%)	5 (27.8%)	20 (19.8%)	0.466
CKD n %	5 (5.7%)	2 (11.1%)	7 (6.6%)	0.746
CHA_2DS_2VASc Score ±SD	1.2 (±1.4)	1.3 (±1.1)	1.3 (±1.3)	0.936
Persistant AF n %	11 (12.5%)	5 (27.7%)	16 (15.1%)	0.05
EF % ±SD	61.5 (±6.3)	56.4(8.7%)	60.7(7%)	0.004
LVEDD (cm) ±SD	4.7 (±0.3)	4.9 (±0.4)	4.7 (±0.3)	0.005
LVESD (cm) ±SD	2.9 (±0.4)	3.2 (±0.7)	2.9 (0.4)	0.005
LA Diameter (cm) ±SD	3,7 (±0.4)	4,2 (±0.4)	3.8 (±0.5)	<0.001
AF Diagnosed Time (month) ±SD	31.9 (±18.7)	36 (±14.4)	32.6 (±18.1)	0.379
Time of the Procedure (minute) ±SD	115.8 (±9)	116.8(±9.6)	95.9(±9.1)	0.649
Fluoroscopy time (minute) ±SD	29.2(±5.5)	26.4(±6.2)	29.2(±5.6)	0.856

AF: atrial fibrillation, BMI: body mass index, CAD: coranary artery disease, CHA2DS2-VASc: Congestive heart failure, Hypertension, Age >_75 years, Diabetes mellitus, Stroke, Vascular disease, Age 6574 years, Sex category (female), CKD: chronic kidney disease, EF: ejection fraction, LA: left atrium, LVEDD: left ventricular end diastolic diameter, LVESD: left ventricular end systolic diameter.

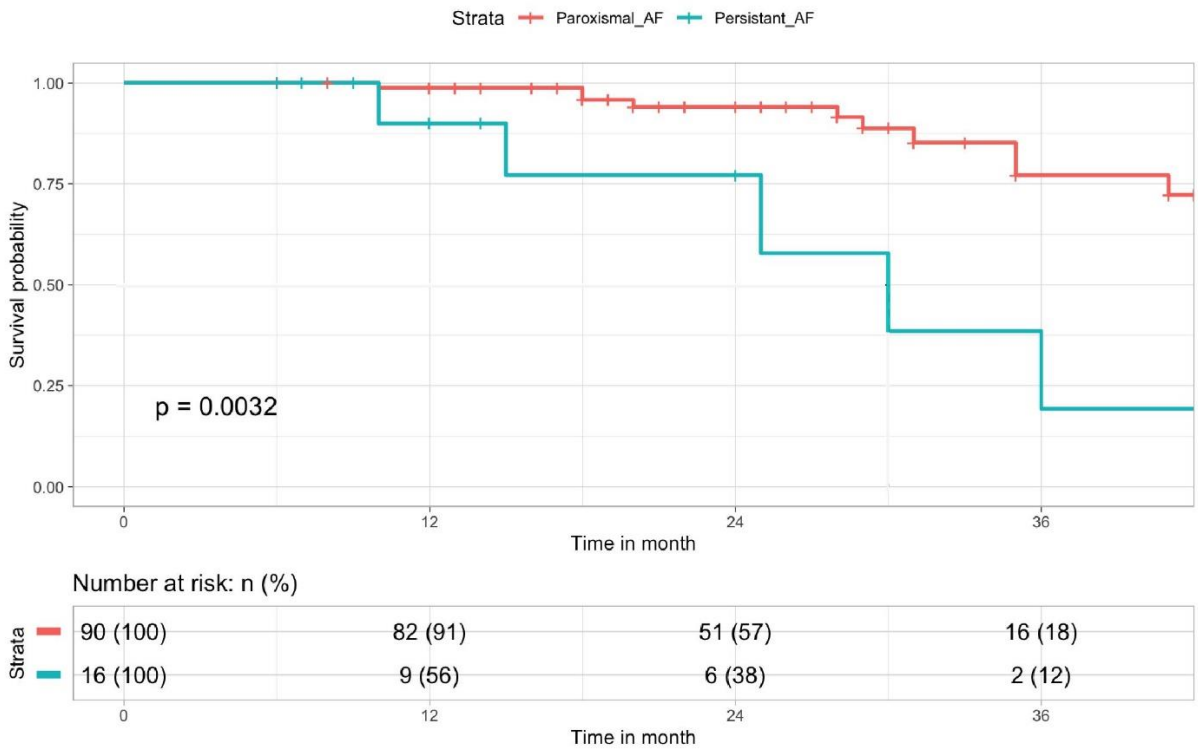

Figure 3. Atrial Fibrillation Free Survival by the Kaplan-Meier Curve (Kaplan Meier curve shows that the reccurence of AF was much more common in patients with persistent AF compared to the patients with paroxysmal AF.)

In this study, there were 416 (8 patients were observed to have common left pulmonary veins) pulmonary veins totally and 412 showed electrical isolation during the procedure (99%). The patients who had non-isolated pulmonary veins during the procedure (4 patients) had early period AF recurrence.

Complications were observed in 8 patients. 3 patients had temporary phrenic nerve paralysis lasting less than 15 minutes, one patient had permanent phrenic nerve paralysis at discharge (It was observed that phrenic nerve paralysis disappeared during the 1st-month control), one patient had minor pericardial effusion, one patient had hematoma that did not require intervention in the femoral region and, one patient had a cerebrovascular event 48 hours after the procedure. The patient who had cerebrovascular event was intervened with percutaneously at an early stage and any

Table 2. Multivariate COX Regression Analyses for Predicting Recurrence of AF

	Univariable HR 95% CI	p	Multivariable HR 95% CI	p
CHA_2DS_2VASc (increase from 0 to 2)	1.18 (0.53-2.65)	0.67	0.72 (0.31-1.68)	0.45
LA diameter (increase from 3.6 to 4.1)	3.38 (1.16-9.87)	0.007	3.63 (1.21-10.84)	0.05*

LA: left atrium.

sequelae were not observed. After the ablation procedure, there was no major bleeding, no major pericardial effusion requiring pericardiocentesis, and no death was observed.

Discussion

This study revealed that after a cryoballoon ablation procedure, 83% of patients were had no AF recurrence in the long-term follow-up. Although AF recurrence was more frequent in patients with persistent AF, our study showed that cryoballoon ablation for atrial fibrillation was effective and reliable in the treatment of paroxysmal AF similar to the results of previous studies[7-10].

AF is the most common atrial arrhythmia and one of the important causes of morbidity and mortality. The EARLY-AF study showed the preference of rhythm control over rate control by catheter ablation in terms of preventing both AF progression and pathophysiological changes in AF patients[11].

In addition, Jais P et al. showed that rhythm control is a more preferable method compared to rate control, and especially the AF catheter ablation may be initially selected in patients with paroxysmal and short-term persistent AF patients[12]. Randomized controlled trials and meta-analyses stated that AF catheter ablation is superior to rate control with antiarrhythmic drugs in the scores of the quality of life.

In addition to these data, there are not enough randomized controlled trials related to stroke, which is a serious cause of mortality and morbidity in the AF ablation patient group[13-17]. The complete pulmonary veins isolation is the main target for AF ablation irrespective of the technique used.

In the literature, no significant dissimilarities were found between cryoballoon ablation and radiofrequency ablation (RFA) in terms of successful PVI. In addition, approaches such as substrate modification and posterior wall isolation that can be applied with RFA are not recommended, especially in patients who underwent AF ablation for the first time[1,18-23]. As known before, in persistent AF, triggers may come from non-pulmonary vein foci (posterior wall, SVC, LAA, CS ostium, etc.) and only pulmonary vein isolation is not sufficient however, in paroxysmal AF, the triggers mostly come from PVI[3,10]. PVI is still the main goal in AF ablation, and wider areas of ablation techniques are not praised in the first-line intervention according to current guidelines. In our study, the majority of patients (84.9%) had paroxysmal AF and only pulmonary vein isolation was determined as a target at the first stage of treatment. The causes of recurrence after AF ablation may be considered as the development of reconnection in the pulmonary veins, another AF triggers out of pulmonary veins, or the extensive scarring of the atrial tissue[24]. AF-free survival was 85.6% for the paroxysmal AF group and 68.8% for the permanent AF group during the follow-up period. Similarly, Boghossian et al. found a recurrence rate of 10.8% for paroxysmal AF and 32.6% for persistent AF in the single-center experience[25].

In contrast to our result, in the CIRCA-DOSE study, in which recurrence was evaluated by implantable monitors, the recurrence rate in proximal AF patients was 36%. We can explain this discrepancy by the fact that, in our study, no implantable loop recorder (ILR) was used in the post-procedural follow-up period (only ECG-Holter and ECG monitoring were performed at certain intervals)[26].

AF type and duration, EF, LA diameter, presence of structural heart disease, hypertension (HT), diabetes mellitus (DM), age, etc. were found as parameters related with AF recurrence after AF ablation[24]. Similarly in our study, in univariate analysis, AF recurrence was found to be associated with EF, ventricle diameters, LA diameter, and the presence of persistent AF. However, in multivariate analysis, only the LA diameter was found to be an independent predictor of AF recurrence. In our study, HT, DM, age, and gender were

not associated with AF recurrence and may be associated with a small number of patients enrolled in the study.

The most common cause of recurrence after cryoablation is the inability to isolate the pulmonary veins during the procedure or reconnection of the pulmonary veins[27,28]. Similarly, in our study, in 4 out of 13 PAF patients who developed AF recurrence, the pulmonary veins could not be electrically isolated during the procedure.

In our study, there was a similar rate of complications (7.5%) with the literature[29,30]. The most common complication was transient phrenic nerve damage that was shown in 4 patients. In addition, one patient developed cerebrovascular disease, one developed pericardial effusion that did not require intervention, and one had vascular complications after the procedure. No death related to the procedure or permanent sequelae were observed in any patient.

Our clinical experience has similar success and complication rates as the other studies in the literature[10,30-34]. As a result, cryoablation, which is less dependent on operator experience and has a shorter processing time can be considered as first-line therapy in PAF patients when the pulmonary veins are considered to be a trigger of AF.

Conclusion

Isolation of PV with cryoballoon seems to be a successful and reliable method of treating AF. In addition to the fact that the chances of success in paroxysmal AF are quite high, it also may be selected to be the first choice of method in persistent AF.

- *Limitations*

The current study has several limitations. First of all, this is a single-center observational study without a control group. Therefore, there might be a bias in patient selection. Secondly, although patients were checked regularly during outpatient clinic visits with ECG, and symptomatic patients were followed with holter monitoring. However, routine holter monitoring was performed only after 1 year of ablation. Therefore, the incidence of AF recurrence may have been underestimated. Lastly, although the median follow-up was 25.2 months, higher AF recurrence may occur after a longer follow-up period.

Author contributions

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Analysis or Interpretation: Ayhan Kup, Mehmet Celik, Abdulkadir Uslu
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Writing: Ayhan Kup, Abdulkadir Uslu

Conflict of interest

The authors declare that they have no conflict of interest.

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Ethical approval

Ethical approval was taken from the Kosuyolu Training and Research Hospital local Ethics Committee, and the principles of the Declaration of Helsinki had carried out (Document No.2020/9/356).

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